EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

← News

ETF warns that monoclonal antibodies may not be effective against emerging strains of SARS-CoV-2

9 December 2022

News Human COVID-19 Medicines

Share

EMA's Emergency Task Force (ETF) has cautioned that monoclonal antibodies currently authorised for COVID-19 are unlikely to be effective against emerging strains of SARS-CoV-2.

These monoclonal antibodies are designed to neutralise the virus by binding to the spike protein on its surface. However, emerging strains have mutations in this protein which can reduce the ability of the antibodies to bind to them.

Recent laboratory studies show that monoclonal antibodies targeting the spike protein are poorly effective at neutralising Omicron strains BA.4.6, BA.2.75.2 and XBB. The data also show that these monoclonal antibodies do not significantly neutralise BQ.1 and BQ.1.1, which are expected to become the dominant strains in the EU in the coming weeks.

Although it is not yet known to what extent the reduced neutralising activity translates into reduced benefits for patients, healthcare professionals will need to consider alternative treatments, especially if subvariants such as BQ.1 and BQ.1.1 become prevalent.

Antiviral treatments such as Paxlovid (nirmatrelvir / ritonavir) and Veklury (remdesivir), which have different mechanisms of action, are expected to retain their activity against the emerging strains. These treatments are approved in the EU for patients with COVID-19 who do not require supplemental oxygen and are at increased risk of their disease progressing to severe COVID-19.

The ETF therefore encourages EU Member States to ensure that healthcare professionals have access to these antiviral treatments for patients at increased risk of severe COVID-19.

The ETF, along with the European Centre for Disease Control and Prevention (ECDC), will continue to monitor the epidemiological situation in the EU. The ETF will also consider recommending an update to the product information for individual monoclonal antibodies.

More about the medicines

A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen).

Four authorised monoclonal antibodies attach to the spike protein of SARS-CoV-2 and by doing so prevent the virus from being able to enter the body's cells. These are Evusheld (tixagevimab / cilgavimab), Regkirona (regdanvimab), Ronapreve (casirivimab / imdevimab) and Xevudy (sotrovimab). EMA has issued advice on the use of a fifth product (bamlanivimab / etesevimab) under Article 5(3) of Regulation 726/2004.

These monoclonal antibodies are used for treating COVID-19 in patients at increased risk of their COVID-19 disease becoming severe and who do not require supplemental oxygen. Some monoclonal antibodies are also approved for preventing COVID-19.

The ETF statement does not refer to RoActemra, another monoclonal antibody, which does not target the virus but acts as a modulator of the immune response and is used with a corticosteroid medicine in patients who require extra

oxygen or mechanical ventilation (breathing assisted by a machine).

More information about other medicines authorised for treating COVID-19, including Paxlovid and Veklury, is available on EMA's COVID-19 treatments page.

Related documents

ETF statement on the loss of activity of anti-spike protein monoclonal antibodies due to emerging SARS-CoV-2 variants of concern

Reference Number: EMA/931457/2022

English (EN) (142.25 KB - PDF)

First published: 09/12/2022

View

Related content

Coronavirus disease (COVID-19)

COVID-19 treatments

Public-health advice during COVID-19 pandemic

COVID-19: latest updates

Emergency Task Force (ETF)

External links

European Centre for Disease Prevention and Control (ECDC)

Contact point

Media enquiries
Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu

All other enquiries
please submit your request via the online form
Follow us on Twitter @EMA_News

Related medicine information

Evusheld

Ronapreve

Xevudy

Regkirona

Paxlovid

Veklury

Share this page

E-mail LinkedIn BlueSky Facebook

More share options

Product emergency hotline
OUTSIDE WORKING HOURS

Glossaries
About this website
Cookies
Website data protection notice
Data protection at EMA

Search tips
Access to documents
Contacts
Send a question
EMA Service Desk (system support)
Services and databases

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Tel: +31 (0)88 781 6000

How to find us
Postal address and deliveries
Business hours and holidays

RSS Feed
Bluesky
YouTube
LinkedIn

© 1995 - 2025 European Medicines Agency

European Union agencies network

An agency of the European Union